

### REMARKS

This is in response to the Office Action mailed August 27, 2003, and is accompanied by a request for a two-month extension of time.

Applicants have noticed that the specification as filed contained incorrect nomenclature, and has been amended to reflect the correct nomenclature. In particular, "(5,5-dimethylborinan-2-yl)" has been corrected to --5,5-dimethyl-[1,3,2]dioxaborinan-2-yl) throughout the specification. No new matter is added, as it would be readily apparent from the synthesis scheme set forth in Example 2 and elsewhere that the dioxaborinan compound was intended and in fact obtained. In addition, other nomenclature corrections are made to pages 26, 34, 36 and 37.

Claim 2 is amended to delete the word "indicator" from the penultimate line thereof, for better antecedent agreement with claim 1. No narrowing of claim scope is intended or believed made.

Claim 18 is amended to add additional compounds. Support is in examples 6 and 10 of the present specification.

Per the Examiner's request, attached hereto are sheets containing the specific structures recited in claim 18.

### Priority Date

As set forth on page 1 of the present specification, the present application is a continuation-in-part of SN 09/754,217 filed January 5, 2001. The present applications also claims the benefit of application Serial No. 60/329,746 filed October 18, 2001 and application Serial No. 60/269,887 filed February 21, 2001.

Present claim 1 is identical to claim 1 of SN 09/754,217, and thus is entitled to an effective filing date of January 5, 2001. Claims 2-17 of the present application are identical to claims 2-17 of SN 60/269,887, and are thus entitled to an effective filing date at least as early as February 21, 2001. Moreover, present claim 2 is substantially identical to claim 2 of SN 09/754,217, differing only in the definition of  $R_9$  and  $R_{10}$ . In particular, present claim 2 adds the alternative under clause iii) that the group can be a functional group capable of altering the physical properties of the compound. However, that concept is disclosed in the specification of SN 09/754,217 in, e.g., Figure 5, in which the group which comprises the lower right portion of the molecule is such a functional group. Therefore, present claims 2-17 are entitled to an effective filing date of January 5, 2001.

Prior to amendment, claim 18 was identical to claim 18 of SN 60/269,887. The compounds added to claim 18 in the present amendment from Example 6 are disclosed in SN 09/754,217, and the compound added to claim 18 from present Example 10 is disclosed for the first time in the present application:

### Double Patenting

Reconsideration and withdrawal of the double patenting rejection of claims 1-17 based on claims 1-18 of application S.N. 10/187,903 are respectfully requested. In view of the amendment to the claims of 10/187,903 filed concurrently herewith, that rejection is believed to be moot.

Reconsideration and withdrawal of the double patenting rejection of claims 1-17 based on claims 1-16 of application S.N. 09/754,217 are respectfully requested. That rejection is believed to be moot, because applicants have not responded to the Office Action mailed March 19, 2003 in that case.

### 35 USC §102

Reconsideration and withdrawal of the rejection of claims 1-18 under 35 USC §102(b) as being anticipated by James are respectfully requested. James fails to disclose all of the claim elements, and therefore cannot anticipate.

The present claims contain the following two elements: i) that the recognition elements are oriented such that the interaction between the compound and glucose is more stable than the interaction between the compound and the alpha-hydroxy acid or beta-diketone, and ii) that the presence of the alpha-hydroxy acid or the beta-diketone does not substantially interfere with the determination of the presence or concentration of glucose. There is no disclosure in James that any of the indicators reported

therein met those requirements. Indeed, the work reported therein with respect to the diboronic acid compound (compound 8; Example 4) relates solely to the detection of glucose in a non-physiological solution (buffered methanol in water). There is no mention of alpha-hydroxy acids or beta-diketones. Consequently, the disclosed James method cannot anticipate the present claims.

While James does disclose that compound 8 is not substantially affected by the presence of galactose or fructose in concentrations which may occur in body fluids, that does not anticipate the presently claimed methods. Galactose and fructose are saccharides, and not alpha-hydroxy acids or beta-diketones. Thus, there is no anticipation.

Additionally, one would not assume that the James diboronic acid compounds would be useful in the presently claimed methods. The Friedman paper of record (JACS, 96:17, 5381--84, August 21, 1974) discloses that phenylboronic acid forms stable 1:1 complexes with lactic acid, an alpha-hydroxy acid (see abstract). Based on that, one would not expect any diboronic acid to detect glucose without interference from lactic acid.

Finally, James does not disclose any of the compounds within the scope of claim 18.

Reconsideration and withdrawal of the rejection of claims 1-13 under 35 USC §102(b) as being anticipated by Bell are respectfully requested. Bell is not a proper reference under 35 USC §102(b) because its April 2, 2002 issue date is later than the December 28, 2001 actual filing date of the present claims. The rejection

is improper and should be withdrawn.

In the interest of completeness, however, applicants state that Bell cannot anticipate the present claims. Bell is relied on as disclosing diboronic acids (e.g., col. 4, lines 20-23). However, Bell does not disclose that such diboronic acids would meet the claim requirements that the recognition elements are oriented such that the interaction between the compound and glucose is more stable than the interaction between the compound and the alpha-hydroxy acid or beta-diketone, and that the presence of the alpha-hydroxy acid or the beta-diketone does not substantially interfere with the determination of the presence or concentration of glucose. The processes disclosed in Bell do not mention alpha-hydroxy acids or beta-diketones, hence Bell cannot anticipate the present claims. Also, based on the Friedman reference of record, one would not assume that the Bell compounds could detect glucose without interference.

Reconsideration and withdrawal of the rejection of claims 1-11 under 35 USC §102(b) as being anticipated by DiCesare are respectfully requested. DiCesare is not a proper reference under 35 USC §102(b) because its June 13, 2001 publication date is not more than one year before the December 28, 2001 actual filing date of the present claims, and is later than the January 5, 2001 and February 21, 2001 effective filing dates of the present claims.

Even if DiCesare were available as prior art, it still would not anticipate any rejected claim. DiCesare is relied on as disclosing diboronic acids (e.g., Figure 1). However, DiCesare

does not disclose that such diboronic acids would meet the claim requirements that the recognition elements are oriented such that the interaction between the compound and glucose is more stable than the interaction between the compound and the alpha-hydroxy acid or beta-diketone, and that the presence of the alpha-hydroxy acid or the beta-diketone does not substantially interfere with the determination of the presence or concentration of glucose. The processes disclosed in DiCesare evaluated glucose detection of two probes (one monoboronic acid and one diboronic acid) in bovine serum albumin and micelles. There is no mention of alpha-hydroxy acids or beta-diketones, hence DiCesare cannot anticipate the present claims. Moreover, based on Friedman, one would not assume that the DiCesare compound could be used to detect glucose without interference.

Reconsideration and withdrawal of the rejection of claims 1-10 under 35 USC §102(b) as being anticipated by Shinkai are respectfully requested. Shinkai is relied on as disclosing diboronic acids (e.g., Structures 6 and 7). However, Shinkai does not disclose that such diboronic acids would meet the claim requirements that the recognition elements are oriented such that the interaction between the compound and glucose is more stable than the interaction between the compound and the alpha-hydroxy acid or beta-diketone, and that the presence of the alpha-hydroxy acid or the beta-diketone does not substantially interfere with the determination of the presence or concentration of glucose. The processes disclosed in Shinkai discussed the detection of

various saccharides (glucose, fructose, and galactose). There is no mention of alpha-hydroxy acids or beta-diketones, hence Shinkai cannot anticipate the present claims. Moreover, based on Friedman, one would not assume that the Shinkai compounds could be used to detect glucose without interference.

**35 USC §112, second paragraph**

Reconsideration and withdrawal of the rejection of claims 1-18 under the second paragraph of 35 USC §112 are respectfully requested. The rejection appears to be based on two grounds: i) that claim 1 defines the compound in allegedly indefinite functional terminology, and ii) that all occurrences of the term "capable of" in claim 2 and elsewhere are improper.

As to the first ground, applicants respectfully submit that the PTO has failed to discharge its burden of proving that the claims lack the clarity required by the second paragraph of 35 USC §112. All that is alleged is that the claim 1 compound is defined solely by functional terminology, but the Action fails to show why the use of such terminology, in a method claim, renders the claims indefinite. To the contrary, it is well settled that there is nothing *per se* wrong with the use of functional terminology in claims:

In our view, there is nothing intrinsically wrong with the use of such a technique [the use of functional language] in drafting patent claims.

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We are convinced that there is no support, either in the actual holdings of prior cases or in the statute, for the proposition, put forward here, that "functional" language, in and of itself, renders a claim improper.

*In re Swinehart*, 169 USPQ 226, 228-29 (CCPA 1971). See also MPEP §2173.05(g). It is respectfully submitted that one of ordinary skill would readily understand what is being claimed by the functional language in claim 1.

As to the second ground, it is respectfully submitted that the PTO has failed to discharge its burden of proving that the "capable of" language is unclear. To the contrary, it is respectfully submitted that one would readily understand what is meant by the language in question, i.e., that the linking group is either attached to a support or matrix, or is capable of such attachment.

As the case is believed in condition for allowance, a favorable Action is respectfully requested.

Respectfully submitted,



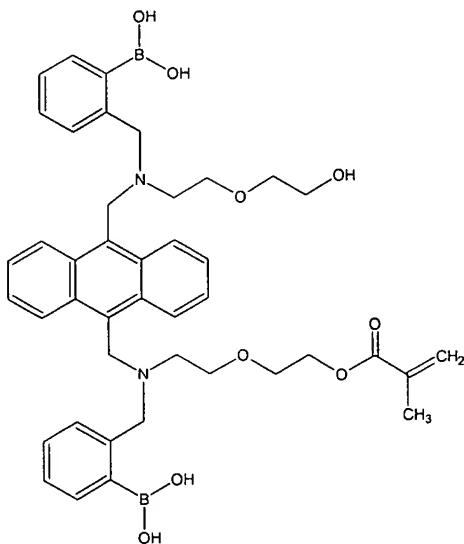
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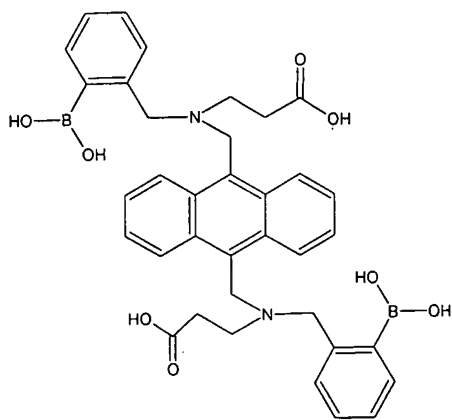


## Structures and Names – Claim 18

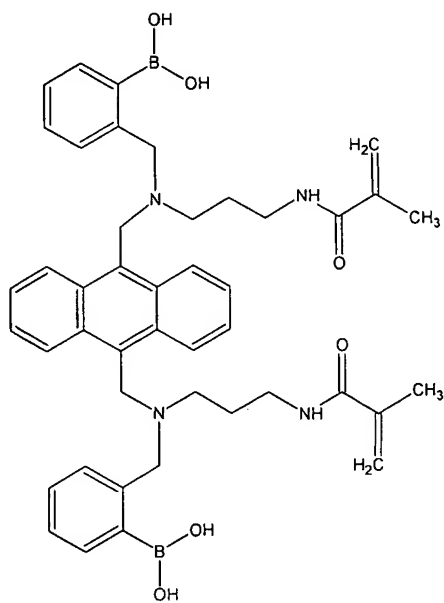
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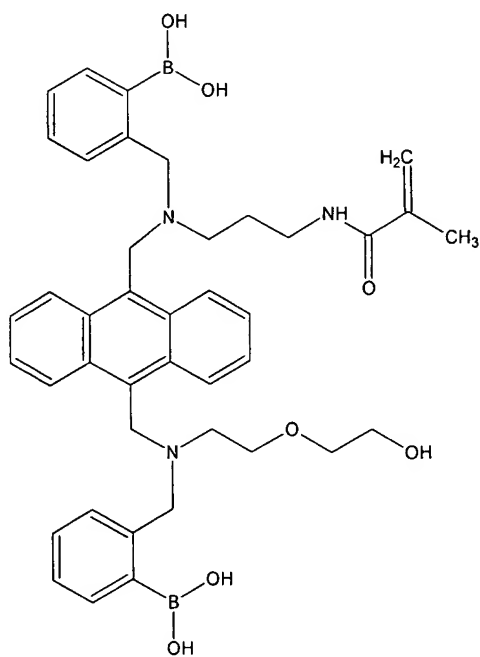
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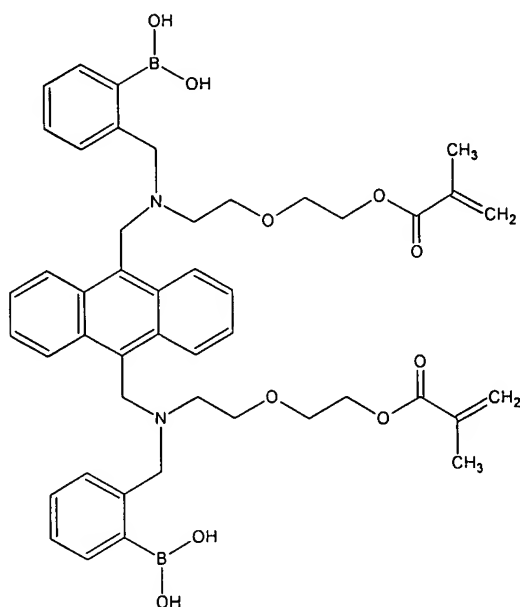
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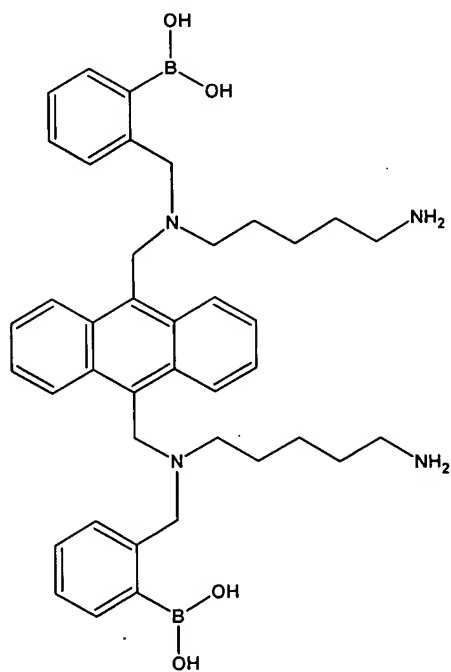
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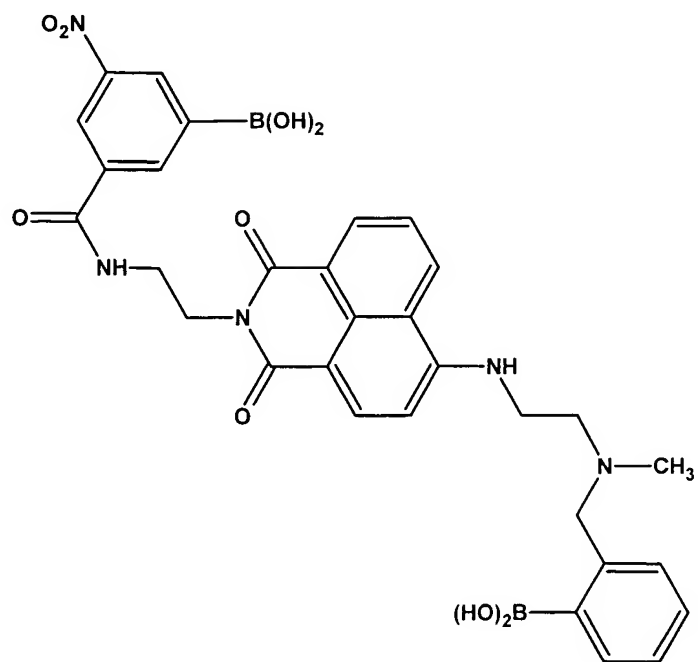
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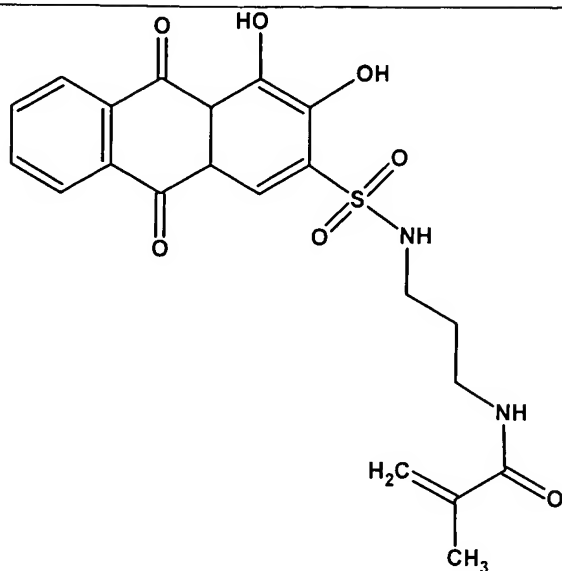
9,10-bis[N-(2-boronobenzyl)-N-[5-aminopentylamino]methyl]anthracene



N-(3-borono-5-nitrobenzamido)ethyl-4-(N'-aminoethylene-N''-[2-(borono)benzyl]methylamino)naphthalene-1,8-dicarboximide



N-[3-(methacrylamido)propyl]-3,4-dihydroxy-9,10-dioxo-2-anthracenesulfonamide



$\alpha,\alpha'$ -bis[N-(2-boronobenzyl)-N-[3-(methacrylamido)propyl]amino]-1,4-xylene

